REMARKS

This is in full and timely response to the above-identified Office Action. The above listing of the claims supersedes any previous listing. Favorable reexamination and reconsideration are respectfully requested in view of the preceding amendments and the following remarks.

Rejections under 35 USC § 103

The rejection of claims 1-4, 6-21 and 23-50 as being unpatentable over Dereume et al. in view of Edwin et al. and further in view of McDonald et al. is respectfully traversed.

In the process of forming the stent of the invention, the stent is entirely covered by the films, and thereafter, a plurality of fine through pores is perforated at portions only where the stent matrix does not exist. Accordingly, the stent is not exposed to blood through the fine through pores in use.

In Dereume et al., the pores are formed by leaching/eluting out particulate matter/polymer solvent from the polymer. For example, column 6, lines 16-27 (part of which is relied on for rejection) sets forth that:

> Cover 43 and/or liner 44 are made of polymers **rendered porous by phase inversion techniques**. In accordance with these techniques, a polymer such as a polyurethane is dissolved in a solvent therefor, for example a water-soluble polar solvent, such as dimethyl acetamide, tetrahydrofuran and the like, in order to form what is known as a lacquer. A mandrel or rod is dipped into the lacquer. Thereafter, the dipped rod is

> contacted with an inversion solvent, such as by dipping in water or a mixture of alcohol and water. **This inversion solvent must readily dissolve the polymer solvent of the lacquer, while at the same time being a poor solvent for the polymer.** Under these conditions, the polymer coagulates and the polymer solvent of the lacquer is removed and replaced with the inversion solvent. **The inversion solvent pulls the polymer solvent out of the polymer on the rod and forms particularly fine pores** having a pore size on the order of about 0.5 micron to about 20 microns. The thus formed liner 44 having phase inversion pores is then dried. (Emphasis added)

Thus it is clear that the pore formation is controlled by the exposure to the solvent and therefore indiscriminate to the degree that it cannot meet or suggest the requirements of only being formed where the stent matrix does not exist.

Edwin et al. contains disclosure of pores in polymer layers but discloses these as a mechanism via which layers can be bonded together and therefore the pores filled in the process. See column 8, lines 34-62 which set forth:

> The **step of fixing the support layer to the biocompatible graft layers comprises selectively applying pressure to the portions of the luminal and abluminal polymer covers after they are loaded onto a mandrel** and then heating the resulting

> assembly at sintering temperatures to form a mechanical bond at the selected areas of applied pressure. Alternatively, a pattern of at least one of an adhesive, an aqueous dispersion of polytetrafluoroethylene, a polytetrafluoroethylene tape, fluoroethylpolypropylene (FEP), or tetrafluoroethylene (collectively the "adhesive") may be introduced between the luminal and abluminal polymer covers at selected positions, followed by heating the assembly to the melt temperature of the adhesive to bond the luminal and abluminal polymer covers while leaving unbonded slip plane regions to accommodate movement of the stent elements. If ultraviolet curable adhesives are used, a UV laser or a photolithography system can be used to create the bond pattern. Many thermoplastic polymers such as polyethylene, polypropylene, polyurethane and polyethylene terephthalate can also be used. If pieces of one of these or similar polymers are placed or attached to one of the polymer covers in the region to be bonded, **heat and pressure will melt the thermoplastic causing it to flow into the pores of the ePTFE, thereby bonding the ePTFE layers together.** (Emphasis added)

The only other reference to pores in Edwin et al. is found at column 14, lines 16-22 which states:

> A number of different activatable adhesive materials can be used in the present invention. One such material might be a layer or coating of a thermoplastic such as polyethylene. **This material can be activated by heat that melts it so that it flows into the pores of the ePTFE.** After cooling the plastic hardens so that the PTFE of **one tubular member is bonded to the other tubular member.** (Emphasis added)

The rejection acknowledges that Edwin et al. does not disclose the use of lasers to form pores. This is not surprising considering the clear intent of Edwin et al. to use pores for interconnection/adhesion purposes. Further, this knowledge for the absence of teachings can only be gleaned from the claims. Nevertheless, irrespective of this reliance on the absence of disclosure, the rejection turns to McDonald et al. to overcome the above admitted shortcoming.

Before dealing with McDonald et al., it must be appreciated that Dereume et al. discloses forming pores everywhere and Edwin et al. discloses using the pores to facilitate bonding of layers together and filling them in the process. These teachings cannot be ignored. Nor can the possibility that the hypothetical person of ordinary skill would possibly be moved to use these teachings in combination for bonding purposes and such as to obliterate the pores in so doing.

However, using the pores of Dereume et al. for connection purposes such as suggested by Edwin et al. would tend strongly to render the Dereume et al. arrangement at least partially inoperable for its intended purpose inasmuch as the pores of Dereume et al.

into which cellular growth is intended, would be removed or blocked. Therefore, there are at least two reasons not to consider the teachings of Dereume et al. and Edwin et al. and therefore no reason that a *prima facie* case of obviousness can be established in light of their respective teachings.

McDonald et al., in this rejection, is used to suggest that lasers could be used to form the pores which are suggested in Dereume et al. It is, however, submitted that this assertion would initially not be applicable to Edwin et al. in that the pores in Edwin et al. are suggested as being naturally occurring and as such an alternative method of forming same would not be given any specific consideration.

In connection with Dereume et al., however, McDonald et al. sets forth that:

> As recited *supra.*, the minimum aperture size should be sufficient to permit endothelial cell growth therethrough. This may be accomplished in apertures having a net cross section measured in microns, with exact limits which can be established through routine experimentation by those of skill in the art. Thus, one hole pattern and distribution pattern for a porous sheet could **involve the use of a laser perforation or other technique for producing hundreds or thousands or more of apertures per square centimeter**. Distribution may be regular or random, **as long as there exists a statistical likelihood that a continuous or tortuous aperture 60 will extend through**

> **each of the adjacent wall layers in the expanded, implanted diameter**, at a distance of no further apart than about 1/8 or 1/10 of an inch as has been discussed.

Now, taken in conjunction with the "jelly roll" construction disclosed in McDonald et al. wherein a single sheet is rolled up like a newspaper and arranged so that, in use, apertures formed in the sheet overlap one another in the rolled-up configuration, it becomes relatively self-evident that the sheet can be perforated in accordance with a predetermined pattern while it is laid out flat and conveniently positioned for laser irradiation, and then rolled up.

There is, therefore, nothing to suggest that laser perforation be used to produce the pores in the tubular configuration such as disclosed in Dereume et al. unless there is some advantage that would suggest itself over the elution technique that is used in Dereume et al. It is submitted that precision relative movement between the stent and the laser source would have to be contemplated simply to achieve a result that can be more simply and repeatedly achieved by dipping/immersion in solvent.

It is submitted that the teachings of Edwin et al. cannot be selectively ignored - the reference must be considered for <u>all</u> that it teaches. Pores are exclusively used for connection purposes. In Dereume et al. the pores are formed by leaching/elution and there is no particular reason to use lasers in the manner disclosed in McDonald et al. unless precisely arranged overlapping apertures were to be deemed necessary - but this would not be the case unless the tubular prosthesis of Dereume et al. were a "jelly roll" configured arrangement which it is not.

Further, the requirement that the apertures or pores be formed only where the stent is not formed is not suggested by the art.

Conclusion

As explained above, the features of the invention are not disclosed or suggested in the cited references. Even if the cited references are combined, claims of the application are not obvious from the cited references.

Reconsideration and allowance are earnestly solicited.

Respectfully Submitted,

By 

Manabu Kanesaka
Reg. No. 31,467
Agent for Applicants

1700 Diagonal Road, Suite 310
Alexandria, VA 22314
(703) 519-9785